

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,098	01/22/2002	Youji Sakagami	4853.0023-02	4190
22852 7	590 04/20/2004		EXAM	INER
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER			GUPTA, ANISH	
LLP 1300 I STREET, NW		ART UNIT	PAPER NUMBER	
WASHINGTON, DC 20005			1654	:
			DATE MAILED: 04/20/2004	1

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
Advisory Action	10/051,098	SAKAGAMI ET AL.				
,	Examiner	Art Unit				
*	Anish Gupta	1654				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address						
THE REPLY FILED 29 March 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.						
PERIOD FOR REPLY [check either a) or b)]						
 a) The period for reply expires 3 months from the mailing date of the final rejection. b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f). 						
Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
1. A Notice of Appeal was filed on Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.						
2. The proposed amendment(s) will not be entered because:						
(a) They raise new issues that would require further consideration and/or search (see NOTE below);						
(b) they raise the issue of new matter (see Note be	pelow);					
(c) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or						
(d) they present additional claims without canceling a corresponding number of finally rejected claims.						
3. Applicant's reply has overcome the following rejection(s):						
4. Newly proposed or amended claim(s) would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).						
5. ☑ The a) ☐ affidavit, b) ☐ exhibit, or c) ☑ request for reconsideration has been considered but does NOT place the application in condition for allowance because: <u>See Continuation Sheet</u> .						
6. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.						
7. For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.						
The status of the claim(s) is (or will be) as follows:						
Claim(s) allowed:						
Claim(s) objected to:						
Claim(s) rejected:						
Claim(s) withdrawn from consideration:						
10. Other:						
		•				

Continuation Sheet (PTOL-303) 10/051,098

Continuation of 5. does NOT place the application in condition for allowance because: of the following reasons. Applicants argue that the position with regards to Friers and Dileone are misplaced because the specification provides the structural information that has a common core and is exemplified in eight examples meeting those limitations. Thus, Applicants content that significant structural information is present in the instant application. Applicants also state that "if processes are sufficient to impart novelty to the claimed peptides, they must be sufficient to adequately describe it" (see page 4 of the response)

Applicants response has been considered but has not been found persuasive.

First, the standard for novelty and obviousness is not the same as the standard ennoblement or written description under 112 First paragraph. Thus, merely because something is novel does not automatically imply that it has be adequately described or enabled to meet the burden under 112 first paragraph. Therefore, Applicants arguments on page 4 of their response has not been found persuasive.

Applicants have also asserted that they have provided significant structural insight and thus provide sufficient written description. Applicants have overlooked the fact that these issues were addressed in the first office action. To reiterate, the MPEP states that for a genus, "The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see i)(A), above), reduction to drawings (see i)(B), above), or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see i)(C), above)."

The specification lacks sufficient variety of species to reflect the variance in the genus since the specification only provides examples of tetra and penta-peptides. Further, these peptides are further limited in that they contain a tyrosine residue in the first and third positions. The specification is void of any peptides that contain structurally distinct acidic amino acids as aspartic acid or glutamic acid as those amino acids contributing to the acidic nature of the peptide. Further, the specification is void of any peptides that have an amino acid length longer than four or five amino acids. Thus, the small genus exemplified does not provide ample written description to any growth factor peptide, regardless of amino acid length, obtained from any liliaceous plant. Thus, the written description requirement has not been met by a representative number of examples.

As for the relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. Although the specification provides some insight as to functional characteristics, the specification does not provide how these functional characteristics correlation between function structure. A growth factor peptide obtained from a liliaceous plants via plant cell cultivation medium is inclusive of numerous peptides. The Liliaceous plant genus is broad and is inclusive of distinct plants such as, onion, garlic, asparagus, tulips, hyacinths, day lily, and aloe. This further increases the number of possible peptides that can be isolated and designated as growth factors. The physio-chemical properties recited in claim 19 do not give any insight into the structure. Properties such as the peptide is acidic and polar, only implies that there is higher number of acidic and polar amino acid, such as aspartic acid, glutamic acid, tyrosine, cystine, asparagine, glutamine, serine, and threonine, present. However, the number of these amino acids can vary since the claim does not recite an amino acid length for the growth factor.

For these reason and the reasons of record, the rejection is maintained.

4/12/04

RAFN

BRENDA BRUMBACK

SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600